REMARKS/ARGUMENTS

Reconsideration of the subject application is respectfully requested. Claims 1-11 and 15-17 are pending in this application.

Turning to the amendments noted above, claims 3 and 11 have been amended in line with the helpful comments of the examiner. Claims 12-14 have been cancelled without prejudice and without acquiescing in the Official Action positions. Claims 15-17 have been added as supported by the specification, for example, page 6, lines 5-30. No new matter has been added by the foregoing amendments.

Turning to the rejections, claims 12-14 stand rejected under 35 U.S.C. §112 and §101. These rejections are moot in view of applicant's cancellation of claims 12-14 without prejudice and without acquiescing in the Official Action positions. Applicant does not agree with the rejections of these claims, but has deleted these claims and has added claims 15-17 in order to further cover the claimed invention in different manners.

Claims 3 and 11 stand rejected under 35 U.S.C. §112. The foregoing amendments to claims 3 and 11 render moot the subject rejection.

Claims 1-12 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Ibrahim (U.S. Patent No. 5,716,988) in combination with Schilpalius (U.S. Patent No. 5,897,871) or Blackshear (U.S. Patent No. 4,439,181). Applicant respectfully requests the withdrawal of the rejection for the following reasons.

The present invention concerns an oxaliplatinum stable pharmaceutical preparation comprising oxaliplatinum contained in a solvent at a concentration of at least 7 mg/ml and wherein the solvent comprises a sufficient quantity of hydroxylated derivative selected among 1,2-propanediol, glycerol, maltitol, saccharose and inositol. Applicants have surprisingly

discovered that the claimed critical concentration (at least 7 mg/ml) in a solvent that comprises a sufficient quantity of a hydroxylated derivative selected among 1,2-propanediol, glycerol, maltitol, saccharose and inositol provides a stable, concentrated pharmaceutical preparation. In other words, applicants have surprisingly discovered that oxaliplatinum at this level of concentration and in this solvent has an unexpected stability in a wide range of utilization temperatures. See, for example, the explanation of these discoveries on pages 2, 3 and 4 of the application. As noted in the specification, this novel and non-obvious preparation is clear, colorless and free of precipitate and remains in this stable form for an extended duration of time.

Neither the primary reference nor the secondary references disclose the claimed composition, concentration or solvents for such a pharmaceutical preparation. Indeed, and as correctly noted in the Office Action, the primary reference Ibrahim "does not expressly teach the exact concentration for the oxaliplatinum nor does the reference teach other solvents for the solution." This clear and unequivocal statement of the deficiencies of the primary reference -- as correctly set forth on page 4 of the Office Action -- highlights the novelty and nonobviousness of the claimed invention.

Moreover, the Ibrahim reference actually teaches away from the claimed invention. In particular, Ibrahim describes a pharmaceutical preparation of oxaliplatinum wherein the oxaliplatinum is dissolved in water at a concentration in the range from 1 to 5 mg/ml, and **preferably** at a concentration of 2 mg/ml. See, column 2, lines 9-13 and lines 2-22 of Ibrahim. Thus, the primary reference Ibrahim teaches away from the claimed invention. To say otherwise would run contrary to the express teachings of Ibrahim and would merely confirm the improper use of hindsight.

The secondary references of Schilpalius and Blackshear do not overcome the deficiencies of the primary reference. Schilpalius does not describe or suggest any method leading to a pharmaceutically stable preparation of oxaliplatinum as claimed in claim 1 of the subject application. This reference merely describes a method for obtaining a beta-carotene composition in an emulsified form. See, for example, column 5, lines 41-49 and column 5, line 53 to column 6, line 11. This disclosure is completely unlike the claimed invention. Moreover, there is no motivation or suggestion in either the primary reference or the secondary reference to combine these two references and end up with the claimed invention. Indeed, as noted above, to modify the primary reference in some fashion and arrive at the claimed invention would run contrary to the express teachings of the primary reference and merely confirm the improper use of hindsight to formulate an obviousness rejection.

Nor does Blackshear overcome the deficiencies of either the primary reference or the other secondary reference. Blackshear does not describe or suggest any composition or method leading to a pharmaceutically stable preparation of oxaliplatinum as claimed in claim 1 of the subject application. Blackshear merely describes a method for maintaining fluidity of protein solutions, for example, insulin solution. Again, like Schlipalius, there is no motivation for a person skilled in the art to combine the oxaliplatinum composition of Ibrahim of from 1 to 5 mg/ml with the Blackshear composition and arrive at the claimed invention – i.e., an oxaliplatinum stable pharmaceutical preparation at a concentration of at least 7 mg/ml and in a solvent that comprises a sufficient quantity of hydroxylated derivative selected from 1,2-propanediol, glycerol, maltitol, saccharose and inositol. Again, only improper hindsight would provide for the combination of Blackshear with the primary reference to render the claimed

invention obvious -- and, moreover, it would run counter to the express and preferred teachings of the primary reference.

For the foregoing reasons and the reasons stated in applicants' Amendment of June 26, 2003, applicants respectfully request the withdrawal of the Section 103 rejection.

Applicants respectfully submit that this case is in condition for allowance and earnestly solicit a notice to that effect. If the examiner has any questions concerning this case, the undersigned may be contacted at 703-816-4009.

Respectfully submitted,

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